

REMARKS

Status of Claims and Amendment

Upon entry of this amendment, claim 6 will be amended. Claims 1-5 are withdrawn as being drawn to a non-elected invention. Claim 6 is rejected.

Claim 6 has been amended to include the recitations “anti-cellulite composition” and “wherein the theanine and at least one active ingredient selected from the group consisting of caffeine, genistein, L-carnitine, and catechin remove cellulite by reducing the activity of glycerol-3-phosphate dehydrogenase (GPDH).” Support for the amendment to claim 6 may be found throughout the specification, for instance, at page 6, lines 6-22, page 7, lines 13-21, Figures 4 to 7, and Experimental Examples 3, 4, 7, and 8.

No new matter is added.

In addition, Applicants thank the Examiner for entering the Amendment filed January 25, 2007.

Applicants reserve the right to file a divisional application directed to non-elected method claims 1-5.

Information Disclosure Statement

Applicants thank the Examiner for acknowledgement of the Information Disclosure Statement filed January 25, 2007, by returning an initialed copy of the PTO/SB/08 form.

Response To Rejections Under §103

Claim 6 is rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,202,222 to Ramazanov et al. (hereinafter “Ramazanov”), with U.S. Patent No. 6,669,952 to Waggle et al. (hereinafter “Waggle”) and further in view of Graham (Prev. Med. 1992 May; 21(3):334-50; hereinafter “Graham”).

The Office Action appears to assert that compositions of Ramazanov may include additional ingredients known for use in promoting weight loss and in treating obesity those used in other weight-loss promoting formulations, e.g., Siberian Rhodiola rosea and Rhaponticum carthamoides root extract, L-carnitine, green tea, citrus extract, and chromium picolinate (see column 8, lines 35-40 of Ramazanov).

The Office Action appears to assert that Waggle teaches a composition comprising a plant sterol and a soy protein material and/or isoflavone selected from genistein, daidzein, glycitein, biochanin A, formononetin, and their naturally occurring glycosides, where the plant sterol is at least 0.49% by weight of the composition. The Office Action also appears to assert that Waggle discloses both a method for decreasing the blood concentration of total and LDL cholesterol and a method for preventing or minimizing the development of atherosclerosis in a human in which the plant sterol and a soy protein material and/or an isoflavone are coadministered to a human, where the plant sterol comprises at least 0.49% by weight, of the combined weight of the plant sterol and the soy protein material and/or the isoflavone.

Waggle allegedly discloses a preferred composition containing an isoflavone material free of soy bean protein and at least 0.49% by weight of plant sterol. The isoflavone is asserted by the Examiner to be genistein, daidzein, glycitein, biochanin A, formononetin, and their naturally occurring glycosides and glycoside conjugates. The plant sterol is asserted to be B-sitosterol, campesterol, stigmasterol, sitostanol, or campestanol (see abstract of Waggle). The Office Action further asserts that Waggle discloses dietary supplements incorporating the plant sterol and the soy protein material and/or the isoflavone which is prepared by adding each of the components to a food as a food ingredient, or by adding a mixture of the components to a food as a food ingredient. (see column 13, lines 8-32 of Waggle).

The Office Action asserts that Graham discloses that green tea components are catechins, caffeine, and theanine (see abstract of Graham).

The Office Action asserts that removing cellulite is an intended use for the composition, and an intended use does not have patentable distinction in a composition claim. The Office Action asserts that the skilled artisan is provided with ample instruction and motivation to use theanine, caffeine, genistein, L-carnitine, and catechin in a composition for removing cellulite.

Ramazanov discloses a composition with ingredients for weight loss including L-carnitine and green tea. Graham is asserted to disclose that the components of green tea are catechins, caffeine, and theanine. Waggle is asserted to use isoflavone, for example, genistein in a dietary supplement for weight loss. The skilled artisan is allegedly motivated to make compositions of the ingredients known for treating obesity, appetite suppressors, and lowering blood cholesterol, because all teachings are asserted to be directed toward removal of excess fat

from the body. The Office Action asserts that one of ordinary skill in the art would have been motivated to combine the teachings of the above references, and the references as combined allegedly teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine the prior arts, since the references teach the same ingredients, genistein, theanine, catechin, caffeine, and L-carnitine that are instantly claimed and are directed to compositions for weight loss.

Applicants submit that the standard for determining whether a patent claiming a combination of prior art elements would have been obvious focuses on “whether the improvement is more than the predictable use of prior art elements according to their established functions.” KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). The reason for combining the elements in the manner claimed may come from sources beyond those contemplated by the applicants, including common sense and common knowledge possessed by one of ordinary skill in the art.

Applicants note that the “mere fact references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.”¹ Also, “[a] statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed

¹ *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.”²

Applicants note that for at least the reasons discussed below, even though the cited documents disclose the individual components, the claimed anti-cellulite composition was not obvious to one of ordinary skill in the art because none of the documents show the unexpected anti-cellulite effect of the claimed composition to remove cellulite by reducing glucose-3-phosphate dehydrogenase (GPDH). A Rule 1.132 Declaration will follow as a supplemental submission to this amendment to show the unexpected effects of claimed invention over the individual components disclosed in Ramazanov, Waggle and Graham.

Applicants note that for example, Figure 6 and Example 7 (page 18, lines 1-19), and Figure 7 and Example 8 (page 18, line 21 to page 19, line 4) show the unexpected slimming and firming effects of the claimed compositions shown in Tables 3 and 4 that is not shown by the components or amounts of components disclosed in Ramazanov, Waggle and Graham.

Also, Figure 2 and Example 2 (page 12, lines 8-20) show an increase in β_3 -adrenergic receptor expression indicative of the effect of 0.005% theanine on decomposing fat. Figure 4 and Experimental Example 4 (page 13, line 19 to page 14, line 4) show the synergistic effects of theanine and catechin on inhibiting neutral fats in fat cells, and Figure 5 and Experimental Example 5 (page 14, lines 7-22) show the synergistic effects theanine, caffeine, genistein, and L-carnitine on decreasing the rate of subcutaneous fat.

² *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993).

Furthermore, in the present case, the Office Action has cited documents that show that the components of the claimed anti-cellulite composition was individually known in the art, however, the Office Action has failed to establish a *prima facie* case of obviousness because none of the documents provide sufficient direction or guidance to provide one of ordinary skill in the art with a reason to combine the components in the manner claimed by the present invention. Contrary to the Office Action’s assertions, it appears the Office Action has used “impermissible hindsight” based on Applicants’ disclosure to reach the legal conclusion that the claimed invention is obvious, rather than based upon the “facts gleaned from the prior art.” (M.P.E.P. §2142). As discussed below, there is nothing in Ramazanov, Graham, nor Waggle to provide one of ordinary skill in the art with an explicit reason to combine the components disclosed in Ramazanov, Graham, and Waggle in the manner claimed.

With regard to Ramazanov, Applicants note that Ramazanov is directed to methods for treating obesity, reducing total weight and reducing body fat mass by administering a composition that includes dihydroquercetins and root-derived aralosides A, B, C, and D. (See abstract of Ramazanov). Dihydroquercetins are flavonoids found in plants such as Grape stem and the leaves of Rhododendron caucasicum and Larix siberica. (See column 3, lines 46-49 of Ramazanov). The dihydroquercetins are found in Engelhardia chrysolepis tea also known as kohki tea. (See column 3, lines 50-51 of Ramazanov). Ramazanov discloses that the combination of dihydroquercetins and aralosides is effective for treating obesity. (See column 4, lines 51-52 of Ramazanov). In addition, Ramazanov discloses a general statement that the compositions of Ramazanov may be combined with other weight loss promoting ingredients,

“for example, *Rhodiola rosea* and *Rhaponticum carthamoides*, root extract, Magnolia bark extract, L-carnitine, green tea, citrus extract, or chromium picolinate.” (See column 9, lines 11-12 of Ramazanov). There is no other disclosure regarding L-carnitine or green tea, nor does Ramazanov provide any teaching that L-carnitine and green tea may be combined with the components disclosed in Graham and Waggle to obtain the claimed anti-cellulite composition comprising theanine and at least one selected from the group consisting of caffeine, genistein, L-carnitine and catechin as active ingredients, wherein the amount of threonine and at least one selected from the group consisting of caffeine, genistein, L-carnitine and catechin is from 0.0001 to 20 wt % based on the total weight of the composition. Accordingly, the Office Action has failed to point to any guidance in Ramazanov, aside from one general statement regarding L-carnitine and green tea, that would provide one of ordinary skill in the art with a reason to combine Ramazanov with Graham and Waggle, in order to obtain the claimed anti-cellulite composition or the claimed method of removing cellulite by administering the claimed composition.

Graham is even less relevant and does not cure the deficiencies of Ramazanov. Graham is an abstract published in 1992 that is generally directed to the composition, consumption, and polyphenol chemistry of green tea, and appears to compare the composition of green tea to black tea, Oolong tea, and fresh leaf tea. (See abstract of Graham). The green tea preparation is disclosed to “preclude the oxidation of green leaf polyphenols. (See lines 5-7 of Graham). Graham discloses that fresh tea leaf is rich in the “polyphenols known as catechins”. (See lines 13-14 of Graham). Graham discloses a general statement that “caffeine is present at an average

level of 3% along with very small amounts of the other common methylxanthines, theobromine and theophylline" (see lines 18-19 of Graham), and that theanine is briefly disclosed to be "unique to tea" (see line 21 of Graham). Accordingly, Graham merely shows that the components of the claimed anti-cellulite composition are known individually in the art, but that a reason to combine Graham with Ramazanov (published in 2007) was not obvious to one of ordinary skill in the art at the time the invention was made or even 15 years later.

Similarly, Waggle is directed to a composition comprising plant sterol and a soy protein material and/or isoflavone. (See abstract of Waggle). Isoflavone is disclosed to be selected from genistein, daidzein, glycinein, biochanin A, formononetin, and their naturally occurring glycosides. *Id.* The composition is disclosed to be used to reduce low density lipoprotein cholesterol and total cholesterol concentrations in the blood, and for preventing or minimizing development of atherosclerosis. (See column 1, lines 9-16 of Waggle). Waggle discloses that genistein is one of the isoflavones that may be combined with the plant sterol and soy protein (see abstract of Waggle), and that isoflavones in general may be added with or without the plant sterol and soy protein material to food as a dietary supplement (see column 13, lines 8-12 of Waggle). However, there is no further teaching to provide one of ordinary skill in the art with a reason to combine Waggle with Ramazanov and Graham.

As discussed above, and explained in a Declaration Under §1.132 to follow, even though the individual components have been disclosed by Graham since at least 1992, the claimed anti-cellulite composition was not obvious to one of ordinary skill in the art because even Waggle (11 years later) and Ramazanov (17 years later), did not combine the components in the manner

claimed. In fact, although Waggle disclosed compositions directed to reducing blood cholesterol and LDL cholesterol, and Ramazanov disclosed compositions directed to reducing body fat mass, neither Waggle nor Ramazanov combined the components as claimed, nor provided guidance or direction to combine the components as claimed. There is nothing in Ramazanov, Waggle, or Graham that motivates or suggests to one of ordinary skill in the art to combine theanine and at least one selected from the group consisting of caffeine, genistein, L-carnitine and catechin as active ingredients.

Furthermore, even if Ramazanov, Waggle, and Graham are combined, the combination would not result in the claimed composition comprising theanine and at least one selected from the group consisting of caffeine, genistein, L-carnitine and catechin as active ingredients, wherein the amount of threanine and at least one selected from the group consisting of caffeine, genistein, L-carnitine and catechin is from 0.0001 to 20 wt % based on the total weight of the composition, or a method of removing cellulite by administering the claimed composition. At most, one of ordinary skill in the art would obtain a composition for reducing body fat mass or for reducing blood cholesterol or LDL comprising dihydroquercetins, root-derived aralosides, a plant sterol, a soy protein material, and/or isoflavone as active ingredients that may optionally be combined with green tea and foods.

CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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